Complete Summary

GUIDELINE TITLE

British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005.

BIBLIOGRAPHIC SOURCE(S)

Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler D, Finlay AY, Griffiths CE, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD, British Association of Dermatologists. British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005. Br J Dermatol 2005 Sep;153(3):486-97. [55 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references drug(s) for which important revised regulatory and/or warning information has been released.

- May 1, 2008, Enbrel (etanercept): Amgen and Wyeth Pharmaceuticals informed healthcare professionals of changes to the BOXED WARNING section of the prescribing information for Enbrel regarding the risk of serious infections, including bacterial sepsis and tuberculosis, leading to hospitalization or death. The ADVERSE REACTIONS section of the label was updated to include information regarding global clinical studies and the rate of occurrence of tuberculosis in patients treated with Enbrel.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Psoriasis

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Dermatology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide useful, evidence-based guidance based on systematic review of literature
- To ensure that the new class of therapy is introduced in a systematic and planned way to achieve the greatest possible benefit to people with psoriasis, to facilitate safe and effective prescribing, and to endorse the use of the British Association of Dermatologists (BAD) Biological Therapy Register as a mechanism for collecting long-term safety and efficacy data

TARGET POPULATION

Adults with psoriasis in the United Kingdom

INTERVENTIONS AND PRACTICES CONSIDERED

1. Selection of patients for biological therapy
2. Anti-tumor necrosis factor (TNF) therapy with etanercept or infliximab

3. Efalizumab therapy
4. Treatment monitoring
5. Assessment and management of adverse treatment effects
6. Use of guidelines on how to prescribe biological therapies
7. Withdrawal of therapy, as indicated

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
- Time to relapse
- Adverse effects and toxicity
- Disease remission
- Quality of life

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature review was performed by searching EMBASE and Medline databases (1990 to April 2005) for clinical trials involving efalizumab, etanercept, and infliximab using an agreed protocol. Two reviewers screened all titles and abstracts independently, and full papers of relevant material were obtained wherever possible. Additional *ad hoc* searches were done to address clinical questions that arose during the development of the guideline, and evidence was appraised in the same manner.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

The published studies selected from the search were assessed for their methodological rigour against a number of criteria as currently recommended by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN). The overall assessment of each study was graded using a code: '+ +', '+' or '-', based on the extent to which the potential biases have been minimized.

1++ High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*

2++ High-quality systematic reviews of case-control or cohort studies

High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal[a]

3 Nonanalytical studies (e.g. case reports, case series)

4 Expert opinion, formal consensus

[a]Studies with a level of evidence '-' should not be used as a basis for making a recommendation.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This guideline has been developed using British Association of Dermatologists (BAD) recommended methodology and the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument. The guideline working group represents all relevant stakeholders including nurses, rheumatologists and patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A At least one meta-analysis, systematic review, or randomized controlled trial (RCT) rated as 1++ , and directly applicable to the target population, or

A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ , directly applicable to the target population and demonstrating overall consistency of results

Evidence drawn from a National Institute for Health and Clinical Excellence (NICE) technology appraisal

B A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, or

Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+ , directly applicable to the target population and demonstrating overall consistency of results, or

Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4, or

Extrapolated evidence from studies rated as 2+ , or

Formal consensus

D (GPP) A good practice point (GPP) is a recommendation for best practice based on the experience of the guideline development group.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft guidance was made available for consultation and review by patients and the British Association of Dermatologists (BAD) membership prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The strength of recommendations (A-D and D[GPP]) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, and 4) are defined at the end of the "Major Recommendations" field.

Which Patients Should be Considered for Biological Therapy?

Eligibility Criteria

To be considered eligible for treatment, patients must have severe disease as defined in (a) **and** fulfil one of the clinical categories outlined in (b):

a. **Severe disease** is defined as a Psoriasis Area and Severity Index (PASI) score of 10 or more (or a body surface area [BSA] of 10% or greater where PASI is not applicable) and a Dermatology Life Quality Index (DLQI)>10. Disease should have been severe for 6 months, resistant to treatment and the patient should be a candidate for systemic therapy. In exceptional circumstances (for example, disabling acral disease), patients with severe disease may fall outside this definition but may be considered for treatment. (**Strength of recommendation D, level of evidence 3**).

AND

b. **Fulfil at least one of the following clinical categories** (**Strength of recommendation B, level of evidence 1++ and formal consensus**):
   i. Have developed or are at higher than average risk of developing clinically important drug-related toxicity and where alternative standard therapy[a] cannot be used
   ii. Are or have become intolerant to or cannot receive standard systemic therapy
   iii. Are or have become unresponsive to standard therapy[b]
   iv. Have disease that is only controlled by repeated inpatient management
   v. Have significant, coexistent, unrelated comorbidity which precludes use of systemic agents such as ciclosporin or methotrexate
   vi. Have severe, unstable, life-threatening disease (erythrodermic or pustular psoriasis)
   vii. Have psoriatic arthritis fulfilling the British Society for Rheumatology (BSR) eligibility criteria for treatment with anti-tumor necrosis factor (TNF) agents, (Kyle, et. al. 2005) in association with skin disease

[a]**Standard systemic therapy** includes acitretin, ciclosporin, methotrexate, narrowband ultraviolet (UV) B and psoralen + UVA photochemotherapy (PUVA)

[b]**Unresponsive to standard therapy** is defined as an unsatisfactory clinical response (a less than 50% improvement in baseline PASI score or percentage BSA where the PASI is not applicable, and a less than 5-point improvement in DLQI) to at least 3 months of treatment in the therapeutic dose range to the following treatments: ciclosporin 2.2 to 5 mg kg^{-1} daily; methotrexate single weekly dose (oral, subcutaneous, intramuscular) 15 mg, max 25 to 30 mg; acitretin 25 to 50 mg daily; narrowband UVB or psoralen photochemotherapy (nonresponse, rapid relapse or exceeding recommended maximum doses) 150 to 200 treatments for PUVA, 350 treatments for narrowband UVB (Ibbotson et. al., 2004; Norris, 1994).

Anti-tumor Necrosis Factor Therapies

Etanercept: Clinical Effectiveness

- Etanercept is effective in the treatment of chronic plaque psoriasis, with 38% and 54% of patients clear or nearly clear of disease after 12 weeks of treatment (25 mg twice weekly, 50 mg twice weekly, respectively). (**Strength of recommendation A, level of evidence 1++**).
- The current license recommends intermittent courses no longer than 24 weeks, with the time to relapse being variable (around 12 weeks) and with similar response rates achieved with repeat dosing.
- Treatment should normally be initiated at 25 mg subcutaneously, twice weekly. However, response is dose dependent and the chances of responding to treatment are greater with 50 mg twice weekly. The choice of the higher dose should be made based on an individual patient basis. (**Strength of recommendation B extrapolated from level of evidence 1++**).
- Treatment may be continued according to clinical need, although long-term efficacy is only established in psoriasis for up to 2 years. (**Strength of recommendation D, level of evidence 3**).

Infliximab: Clinical Effectiveness

- Infliximab is effective in the treatment of chronic plaque psoriasis, with 90% of patients becoming clear or minimally affected at 10 weeks following 5 mg kg^{-1} at weeks 0, 2 and 6. (**Strength of recommendation A, level of evidence 1++**).
- Infliximab therapy may be initiated at a dose of 5 mg $kg^{-}1$ at weeks 0, 2, and 6 and subsequent maintenance infusions (either 5 mg kg^{-1} or 3 mg kg^{-1}) given at 8-week intervals depending on clinical need and circumstances. (**Strength of recommendation A, level of evidence 1++**).
- In those patients who respond to therapy, regular maintenance infusions may avoid the risk of loss of efficacy seen in some patients receiving intermittent as-required repeat infusions on disease relapse. (**Strength of recommendation D, level of evidence 3**).
- Infliximab may also be of value in recalcitrant or unstable disease and in generalized pustular psoriasis. (**Strength of recommendation D, level of evidence 3**).
- Concomitant systemic therapies may be indicated for some patients with very severe or unstable psoriasis, although doses of these should be minimized. (**Strength of recommendation D, level of evidence 3**).

Adverse Effects and Toxicity: Anti-TNF Therapies

Infection and Anti-TNF Agents

- Actual risks of serious infections are unknown, particularly in those with psoriasis. Concomitant treatment with immunosuppressants or human immunodeficiency virus (HIV) infection may increase any risk. (**Strength of recommendation D, level of evidence 3**).
- Reactivation of tuberculosis may occur following treatment with anti-TNF agents, and the risks are greatest with infliximab. There appears to be a disproportionate risk of nonpulmonary and disseminated infection. (**Strength of recommendation D, level of evidence 3**).

- Patients with evidence of either active tuberculosis or previous, inadequately treated tuberculosis should receive antituberculous treatment prior to anti-TNF therapy (Ormerod, 2004; Ormerod and Joint Tuberculosis Committee of the British Thoracic Society, 2005) (**Strength of recommendation D, level of evidence 4**).

Heart Disease and Anti-TNF Agents

- Anti-TNF agents should be avoided in patients with severe (New York Heart Association [NYHA] class III or IV) congestive heart failure. (**Strength of recommendation D, level of evidence 4**).
- Those with milder disease should be carefully assessed prior to treatment, and treatment withdrawn at the onset of new symptoms or worsening of pre-existing heart failure. (**Strength of recommendation D, level of evidence 4**).

Demyelination and Anti-TNF Agents

- Infliximab and etanercept should not be given to people with a history of demyelinating disease or optic neuritis and treatment should be withdrawn if neurological symptoms develop. (**Strength of recommendation D, level of evidence 4**).

Hepatitis and Anti-TNF Agents

- The safety of TNF blockers in patients with chronic hepatitis B and C is not known. For patients known to be hepatitis B or C positive, advice from a hepatologist should be sought prior to initiation of therapy. (**Strength of recommendation D, level of evidence 4**).

Efalizumab

Clinical Effectiveness

- Efalizumab is effective in the treatment of moderate to severe chronic plaque psoriasis, with approximately one third of patients treated becoming clear or almost clear after 12 weeks. (**Strength of recommendation A, level of evidence 1++).**
- Duration of remission is variable on discontinuing therapy and may be associated with disease rebound. (**Strength of recommendation D, level of evidence 4**).
- The licensed weekly dose (1 mg kg^{-1}) should be used and treatment discontinued after 12 weeks in those who do not respond. (**Strength of recommendation A, level of evidence 1++**).
- Therapy may be continued according to clinical need although data on long-term efficacy are limited to 27 months. (**Strength of recommendation D, level of evidence 4**).

Choice of Agent to Use

- Choice of agent efalizumab, etanercept, or infliximab, will depend on the clinical pattern of psoriasis, pre-existing comorbidity, patient preference, prescriber preference and local facilities.
- Etanercept should be considered first choice for patients with significant, uncontrolled psoriatic arthritis (refer to BSR guidelines here [Kyle et. al., 2004] but for this guideline skin disease identifies patient need). (**Strength of recommendation D, level of evidence 4**).
- For patients with stable psoriasis where a decision has been made to treat with an anti-TNF agent, etanercept should be used unless there are clear reasons not to do so. (**Strength of recommendation D, level of evidence 4**).
- Infliximab is useful in clinical circumstances requiring rapid disease control (e.g. in unstable erythrodermic or pustular psoriasis) due to its very rapid onset of action and high response rate. (**Strength of recommendation D, level of evidence 4**).
- For patients with a high risk of latent tuberculosis (and therefore requiring tuberculosis prophylaxis) or with evidence of demyelinating disease, efalizumab should be considered first choice. (**Strength of recommendation D, level of evidence 4**).

How to Prescribe Biological Therapies

Role of Specialist Nurse

Safe prescribing of biological therapies requires good infrastructure and specialist nursing personnel. With additional training a nurse may take responsibility for a number of the tasks outlined in the patient pathway including screening, treatment administration, patient education, prescription coordination for home drug delivery, patient support, monitoring, and data collection (e.g. PASI). A list of core competencies including cannulation skills is suggested by the Royal College of Nursing for rheumatology nurses involved in biological therapies.

Patient Information and Consent

Patients should be fully informed of the risks and benefits of biological therapies through detailed, collaborative discussion with the supervising consultant and clinical nurse specialist. Written information should be provided (available on the British Association of Dermatologists [BAD] website) and patients given adequate time to consider their decision. In clinical circumstances where these therapies are being used outside their licensed indications, written consent should be obtained.

Registration

In the interest of acquiring long-term safety data a comprehensive national register is proposed. Once this is operative (expected in early 2006), all patients should be registered and followed up through this register.

Pretreatment Assessment

All patients should undergo a full clinical history, physical examination and further investigations as required, with particular reference to the known toxicity profile of the agent being considered.

Specific exclusion criteria and recommended pretreatment investigations are listed in the tables below. Assessment for risk of tuberculosis in patients considered for anti-TNF therapy is detailed in Figure 1 of the original guideline document.

Exclusion Criteria for Anti-tumor Necrosis Factor (TNF) Agents and Efalizumab

Pregnant or breast feeding

Active infections. High risk include:

- Chronic leg ulcers
- Persistent or recurrent chest infections
- Indwelling urinary catheter

Latent tuberculosisa* (see Figure 1 of the original guideline document)

Malignancy or premalignancy states excluding:

- Adequately treated non-melanoma skin cancer
- Malignancies diagnosed and treated more than 10 years previously (where the probability of total cure is very high)

Demyelinating disease[a]

Congestive cardiac failure[a]

(New York Heart Association grade III or IV, see Table 1 of the original guideline document)

Relative contraindications:

- Psoralen + ultraviolet A therapy > 200 treatments, especially when followed by ciclosporin therapy
- Human immunodeficiency virus-positive or Acquired Immunodeficiency Syndrome (AIDS)
- Hepatitis B or C virus-positive

[a]These apply to anti-TNF agents only.

Recommended Pretreatment and Monitoring Investigations

		Pretreatment[a]	Monitoring[a]
Disease severity assessment			

Skin	PASI DLQI	Yes	At 3 months, then every 6 months
Joints (Where applicable)	Follow recommended BSR guidelines for psoriatic arthritis	Yes	At 3 months, then every 6 months
General health (symptom enquiry and clinical examination)	Infection Demyelination[b] Heart failure[b] Malignancy (including skin)	Yes	At 3-6 month intervals
Assessment for latent tuberculosis[b]	See Figure 1 of the original guideline document		
Blood tests	Full blood count	Yes	Efalizumab: monthly for the first 3 months, then every 3 months Tumour necrosis factor blockers: at 3 months, then every 6 months
	Creatinine, urea and electrolytes, liver function tests	Yes	At 3 months, then every 6 months
	Hepatitis B and C	Yes	-
	Human immunodeficiency virus	Consider testing in those at risk	-
	Autoantibodies[b] (antinuclear antibodies, antidouble-stranded DNA antibodies)	Yes	-
Urine	Urine analysis	Yes	At 3 months, then every 6 months

Radiology	Chest X-ray	Yes	-

PASI, Psoriasis Area and Severity Index; DLQI, Dermatology Life Quality Index; BSR, British Society for Rheumatology.
[a]Additional assessment and monitoring may be required in patients on concomitant therapy or in certain clinical circumstances.
[b]Applies to tumour necrosis factor blockers only.

Monitoring and Assessment of Disease Response

Patients should be seen at 12 weeks to determine whether therapy should be continued, and thereafter at 3-6-monthly intervals. The need for monitoring biochemistry and haematology is less than that required for conventional drug therapies (see table above) with the exception of platelet counts for patients on efalizumab. However, regular review of the clinical status of the patient is essential to ensure early detection of adverse effects, particularly infection.

Adequate Response to Treatment

This is defined as a 50% or greater reduction in baseline PASI score (or percentage BSA where the PASI is not applicable) and a 5-point or greater improvement in DLQI within 3 months of initiation of treatment.

Where arthritis has determined eligibility for treatment, please refer to the BSR guideline for psoriatic arthritis for the definition of treatment response.

Withdrawal of Therapy

Therapy should be withdrawn after 3 months if there has not been at least a 50% improvement in baseline PASI score (or percentage BSA where the PASI is not applicable) and a 5-point or greater improvement in DLQI. Withdrawal of therapy is also indicated due to the development of a serious adverse event. Adverse events which may justify the withdrawal of treatment include the following: malignancy (excluding nonmelanoma skin cancer); severe drug-related toxicity; pregnancy (temporary withdrawal); severe intercurrent infection (temporary withdrawal); major surgical procedures (temporary withdrawal in accordance with updated BSR guidelines).

Definitions:

Strength of Recommendations

A At least one meta-analysis, systematic review, or randomized controlled trial (RCT) rated as 1++ , and directly applicable to the target population, or

A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ , directly applicable to the target population and demonstrating overall consistency of results

Evidence drawn from a NICE technology appraisal

B A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, or

Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+ , directly applicable to the target population and demonstrating overall consistency of results, or

Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4, or

Extrapolated evidence from studies rated as 2+ , or

Formal consensus

D (GPP) A good practice point (GPP) is a recommendation for best practice based on the experience of the guideline development group

Level of Evidence

The published studies selected from the search were assessed for their methodological rigour against a number of criteria as currently recommended by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network. The overall assessment of each study was graded using a code: '+ +', '+' or '-', based on the extent to which the potential biases have been minimized.

1++ High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*

2++ High-quality systematic reviews of case-control or cohort studies

High-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal*

3 Nonanalytical studies (e.g. case reports, case series)

4 Expert opinion, formal consensus RCT, randomized controlled trial

* Studies with a level of evidence '-' should not be used as a basis for making a recommendation.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided in the original guideline document for the assessment and management of tuberculosis (TB) in patients scheduled for anti-tumor necrosis factor (TNF) therapy.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded for each recommendation (see Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Safe and effective prescribing of biological therapies for psoriasis
- Improved clinical effectiveness
- Decreased time of relapse
- Increased disease remission
- Improved quality of life
- Decreased long-term toxicity

POTENTIAL HARMS

Anti-Tumor Necrosis Factor (TNF) Agents

- Allergic reactions, including injection site reactions (frequently reported) and anaphylactic shock (rare)
- Serious and opportunistic infections, including tuberculosis, sepsis secondary to *Listeria monocytogenes* and histoplasmosis
- Severe disseminated opportunistic infections in patients who are human immunodeficiency virus (HIV) positive
- Cardiovascular disease (new onset or worsening of pre-existing heart failure)
- Neurological disease (development of or worsening of demyelinating disease; worsening of multiple sclerosis)
- Development of antinuclear antibodies and lupus-like syndrome
- Hepatitis (rare)

Note: Safety data for anti-tumor necrosis factor (TNF) agents so far do not indicate increased rates of malignancy, including lymphoproliferative disorders, over the normal rates in the population. Patients who have received psoralen +

ultraviolet (UV)A photochemotherapy (PUVA) may represent a particular at-risk group.

Efalizumab

- Influenza-like symptoms
- Thrombocytopenia
- Transient, acute, pruritic eruption and flares of psoriasis

Note on potential risk of serious infection and malignancy with efalizumab therapy: There is no evidence so far that the rates of serious infection are increased. Similarly, rates of malignancy are no greater in those treated compared with controls, but the data are too limited to assess this risk properly.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Following severe allergic reactions to infliximab, further infliximab treatment is contraindicated.
- See "Exclusion criteria for anti-tumor necrosis factor (TNF) agents and efalizumab" in the "Major Recommendations" field.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines were developed in accordance with a predetermined scope, agreed by the guideline working group, For practical reasons, guidance is given only on those treatments that are currently licensed for use in psoriasis in the United Kingdom (U.K.) (etanercept, efalizumab) and infliximab. Although infliximab is currently unlicensed for use in psoriasis, a license is anticipated in the near future, it is widely available, and it is currently the most extensively used biological therapy in dermatology clinical practice.
- These guidelines have been prepared for dermatologists on behalf of the British Association of Dermatologists (BAD) and reflect the best data available at the time the report was prepared. Caution should be exercised in interpreting the data; the results of future studies may require alteration of the conclusions or recommendations in this report. It may be necessary or even desirable to depart from the guidelines in the interests of specific patients and special circumstances. Just as adherence to guidelines may not constitute defence against a claim of negligence, so deviation from them should not necessarily be deemed negligent.
- The guideline group has sought to provide useful, evidence-based guidance based on systematic review of available literature, but acknowledges that additional funding may be required to implement guideline recommendations fully.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Smith CH, Anstey AV, Barker JN, Burden AD, Chalmers RJ, Chandler D, Finlay AY, Griffiths CE, Jackson K, McHugh NJ, McKenna KE, Reynolds NJ, Ormerod AD, British Association of Dermatologists. British Association of Dermatologists guidelines for use of biological interventions in psoriasis 2005. Br J Dermatol 2005 Sep;153(3):486-97. [55 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Sep

GUIDELINE DEVELOPER(S)

British Association of Dermatologists - Medical Specialty Society

SOURCE(S) OF FUNDING

British Association of Dermatologists

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflicts of interest: C.H.S., grant/research trial support Wyeth, Serono, Schering Plough, consultant for Novartis; A.V.A., consultant for Schering Plough; J.N.W.N.B., consultant for Schering Plough, Wyeth, Biogen, Serono Novartis; grant/research trial support Schering Plough, Wyeth, Biogen, Serono; A.D.B., consultant for Wyeth, Serono, Schering Plough; grant/research trial support Wyeth, Serono; R.J.G.C., none; D.C., none; A.Y.F., consultant for Wyeth, Novartis, Serono, Amgen, Abbott; trial support; C.E.M.G., grant/research support Biogen, Serono, Amgen, Centocor; previous consultant for Serono, Wyeth, Schering Plough; K.J., none; N.J.McH., consultant for Aventis, Abbott; grant/research support Wyeth; K.E.McK., none; N.J.R., grant/research support Serono; A.D.O., grant/research support Wyeth, Serono.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the British Association of Dermatologists Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Psoriasis - an overview. Patient information leaflet. London (England): British Association of Dermatologists; 2005 Mar. 6 p. Available from the British Association of Dermatologists Web site.
- Treatments for moderate or severe psoriasis. Patient information leaflet. London (England): British Association of Dermatologists; 2005 Mar. 12 p. Available from the British Association of Dermatologists Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on May 11, 2007. The information was verified by the guideline developer on June 13, 2007. This summary was updated by ECRI Institute on May 15, 2008 following the U.S. Food and Drug Administration advisory on Enbrel (etanercept).

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